LWG
LOWER WILLAMETTE GROUP

Via Federal Express

July 23, 2012

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Re: Notice of Objection to EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution
Lower Willamette River, Portland Harbor Superfund Site, USEPA Docket No: CERCLA-10-2001-0240

Dear Chip and Kristine:

On June 22, 2012, EPA provided a redlined version of the main text and certain attachments to the Lower Willamette Group's May 2, 2011 draft final Baseline Human Health Risk Assessment (BHHRA) ("June 22 letter"). The June 22 letter directed the LWG to revise the BHHRA consistent with the accompanying redline and with additional directed comments on tables and figures to the BHHRA. EPA's cover letter states that "EPA has determined that the LWG failed to produce a BHHRA of acceptable quality, or otherwise failed to perform in accordance with the requirements of the Order by failing to fully correct all deficiencies and incorporate all information and comments supplied by EPA on prior versions of the BHHRA." In its follow-up letter dated June 29, 2012 ("June 29 letter"), EPA stated that stipulated penalties are accruing as of June 22 because the BHHRA was not of acceptable quality.

Pursuant to § XVIII of the September 28, 2001 Administrative Settlement Agreement and Order on Consent (Consent Order), the LWG hereby initiates dispute resolution with regard to (1) EPA's June 22, 2012 determination that the LWG "failed to produce a BHHRA of acceptable quality, or otherwise failed to perform in accordance with the requirements of the Order" and (2) EPA's June 22, 2012 directed revisions to the BHHRA's text, tables, and figures. The LWG's objections and the bases for those objections are stated below and in the enclosed tables.

The LWG strongly disagrees with and objects to EPA's directed revisions to the draft final BHHRA, EPA's determination that the LWG has failed to comply with the Consent Order, and the potential imposition of stipulated penalties. In the interest of streamlining the dispute, the LWG has provided representative examples rather than an in-depth submittal for each directed revision. LWG hereby reserves its right to supplement the record with more specific substantive responses to each of the redlined changes and comments on the tables and figures that are new, inconsistent or otherwise without technical or substantive merit.

The LWG does not expect the dispute resolution process to interfere with EPA's review of the draft Feasibility Study submitted on March 30, 2012. EPA has committed to the Portland community that it intends to prepare a proposed plan and issue a Record of Decision by 2014, and EPA has separate technical staff members assigned to the draft FS and BHHRA.

The BHHRA faithfully reflects EPA's extensive prior comments and agreed upon resolutions

The BHHRA was the subject of extensive review by, and repeated comments from, EPA. Between December 2009 and July 2010, EPA provided more than 200 comments on the October 2009 draft BHHRA. EPA's July 16, 2010 cover letter transmitting these comments, as well as several hundred additional comments on the draft Remedial Investigation Report and draft Baseline Ecological Risk Assessment, stated that EPA was providing its "complete set of comments" on the draft RI and baseline risk assessments and had "attempted to provide clear direction on the specific revisions that are needed to resolve the comments." EPA and the LWG thereafter engaged in several months of detailed technical negotiations to resolve EPA's comments. The resolution of all of EPA's comments was documented in tables generated by the LWG and acknowledged by EPA as follows:

- LWG *General Responses to EPA Directive Comments on the Baseline Human Health Risk Assessment*, September 15, 2010 (acknowledged by EPA letter dated September 22, 2010)
- LWG *General Responses to EPA Non-Directive Comments on the Baseline Human Health Risk Assessment*, November 18, 2010 (acknowledged by EPA letter dated December 8, 2010)
- LWG *Response to EPA's General Comments on the RI, BHHRA and BERA*, January 12, 2011 (acknowledged by EPA letter dated February 25, 2011).

EPA's letters acknowledging the written resolution of the comments are clear and unambiguous. The LWG relied on and complied with the written resolutions, as well as pertinent EPA national risk assessment guidance, in preparing the revised version of the BHHRA. EPA's June 22, 2012 letter and the directed revisions to the BHHRA entirely disregard these agreements to resolve EPA's comments on the BHHRA, which EPA advised LWG were its "complete set of comments" necessary to finalize the BHHRA.

A detailed compilation of the instances in which EPA's June 22 revisions to the draft BHHRA either fail to honor EPA's agreements with the LWG or are inconsistent with EPA's own prior comments and directed changes on the BHHRA is provided in the enclosed Tables 1

and 2.[1] EPA's comments on the October 2009 draft BHHRA, documentation of EPA and LWG agreements related to the revision of the BHHRA, and the May 2, 2011 draft final BHHRA, redlined to show changes in response to EPA comments on the October 2009 draft, are attached at Tabs 1 through 17.[2]

The LWG was surprised at the scope and magnitude of EPA's comments, given the previous substantive resolutions. The LWG had no reason to believe, then or now, that EPA was reversing the written resolutions of comments it had previously negotiated with the LWG. We are hopeful that the positions stated in EPA's June 22 and 29 letters are inadvertently in conflict with EPA's prior directions and that EPA will simply withdraw those letters and revise its comments such that they are consistent with and honor EPA's prior direction.

EPA's change of its prior approach and documented resolution is arbitrary and capricious

EPA's change of its prior negotiated and approved approach to developing the BHHRA and its abandonment of existing agreements with the LWG constitutes arbitrary and capricious agency action in violation of the Administrative Procedure Act. "[A]n agency acts arbitrarily and capriciously when it abruptly departs from a position it previously held without satisfactorily explaining its reason for doing so." *Wisconsin Valley Improvement Company v. Federal Energy Regulatory Commission*, 236 F. 3d 738, 748 (D.C. Cir. 2001). *See also, Northwest Environmental Defense Center v. Bonneville Power Administration*, 477 F.3d 668, 687 (9th Cir. 2007), *quoting Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970) ("an agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored...."); *Sierra Club v. Jackson*, 833 F.Supp.2d 11, 32 (D. D.C. 2012), *quoting Jicarilla Apache Nation v. U.S. Department of the Interior*, 613 F.3d, 1112, 1120 (D.C. Cir. 2010) (" '[a]n agency's failure to come to grips with conflicting precedent constitutes an inexcusable departure from the essential requirement of reasoned decisionmaking.' EPA has failed ... to come to grips with its prior precedents. For that reason the Delay Notice is arbitrary and capricious."); *Sierra Club North Star Chapter v. LaHood*, 693 F.Supp.2d 958, 973 (D. Minn. 2010) ("A failure to acknowledge [National Park Service's] previous position, let alone explain why, in NPS's opinion, a change is justified, is the hallmark of an arbitrary and capricious decision.")

The LWG has complied with the Consent Order

EPA's assertion that the LWG is not in compliance with the Consent Order because of what appears to be EPA's arbitrary and unexplained change of mind is unreasonable. Although Tables 1 and 2 provide conclusive evidence of why EPA should retract this determination immediately, we highlight below the lack of any merit in the four "deficiencies" EPA's June 22 letter identifies in support of its determination that the LWG has failed to comply with the Consent Order.

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[1] On June 29, 2012, EPA denied the LWG's request for a 30 day extension to prepare for dispute resolution, allowing the LWG only 14 additional days to review and evaluate over 200 pages of EPA revisions to a document EPA had under review for approximately 14 months. The LWG reserves the right to supplement the materials provided with this letter.

[2] Because EPA's comments on the BHHRA and the agreed resolution of those comments amount to nearly 1400 pages, the LWG is providing the documentation supporting this letter and Tables 1 and 2 on a CD, rather than in hard copy. If EPA would like paper copies of this backup documentation, please let us know.

First, EPA finds that the BHHRA provided "incorrect or misleading information." EPA provides a single example in support of this finding:

> "[T]he BHHRA repeatedly stated that the exposure assessment assumed someone ate fish every day of the year for 30 years. The LWG is fully aware that such a statement is not accurate.... EPA commented on this issue in our February 9, 2010 comment letter; however, the LWG failed to address it."

As an initial matter, EPA commented on this issue in its July 16, 2010 comments; its February 9, 2010 letter does not address this topic at all. EPA's July 16, 2010 comments request five specific edits to text in the BHHRA (comments S91, S96, S143, S150, and S179).[3] Only two of these five comments (S96 and S150) were identified by EPA as "directed changes."[4] In fact, however, the LWG revised the text in all five instances precisely as EPA requested.[5]

Second, EPA finds that "the BHHRA does not fully reflect EPA's directions for change, directions given years before and reiterated in our comments to prior versions." As its single example, EPA quotes a "February 2010 comment" related to the description of exposure point concentrations. Again, this comment is found in EPA's July 16, 2010 comment letter, not the February 2010 letter. And again, this comment (S52) is identified by EPA as "clarify," not as "directed change."[6] Finally, there was a specific agreement between EPA and the LWG as to how to resolve comment S52. That resolution is documented in the LWG's November 18, 2010 *General Responses to Non-Directed Comments on the BHHRA* and was acknowledged by EPA on December 8, 2010.[7] In part, the LWG and EPA agreed that "the EPC will be identified as the mean, 95% UCL or maximum." [8] Notwithstanding this agreement, EPA now concludes that the BHHRA is "deficient" because it includes EPCs based on the arithmetic mean. Clearly, this cannot be the basis of any deficiency, because the BHHRA text faithfully reflects the documented agreement on comment S52. Therefore, EPA's finding of "deficiency" on this point is incorrect in at least three particulars: (1) the comment was not made in February 2010; (2) it was not a directed change; and (3) the May 2, 2011 draft final BHHRA is consistent with the November 18, 2010 agreed resolution of that comment.

Third, EPA finds the BHHRA deficient because "[t]here were many instances in the BHHRA where the only explanation the LWG provides for why something is done was that EPA directed or otherwise required it be done."[9] This is an entirely new comment on the BHHRA,

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[3] See, Table 1. EPA's July 16, 2010 comments on the BHHRA are at Tab 8.
[4] *Id.* at p. 150.
[5] See, May 2, 2011 Draft Final RI Report Appendix F BHHRA Main Text redline, attached at Tab 15, pp. 114, 117, 121, 155, 156, 175, and 176.
[6] July 16, 2010 comments on the BHHRA, pp. 52-53 (at Tab 8).
[7] November 18, 2010 *General Responses to EPA's Non-Directive Comments on the* BHHRA at p. 6 (at Tab 11); EPA December 8, 2010 letter (at Tab 12).
[8] Note that the Programmatic Work Plan (approved by EPA on June 29, 2004) states, "...the arithmetic mean concentrations will be used as EPCs for individual sampling locations" and "[s]ite-wide tissue EPCs will also be estimated using mean concentrations..." Programmatic Work Plan, Appendix C, page 26. While EPA guidance recommends using the 95 percent UCL to estimate the EPC, DEQ rules require use of the arithmetic mean concentration as an EPC. OAR 340-122-0084(1)(g). Therefore, both calculations were performed in the BHHRA.
[9] EPA's June 22 revisions actually delete all references to assumptions or evaluations in the BHHRA being directed by EPA. This revision itself violates EPA's agreement with the LWG that "language stating that evaluations were done at the direction of EPA can remain in the revised BHHRA. Language implying opinion or judgment about the prudence of that direction will be removed." September 15, 2010 *General Responses to Directed Comments on BHHRA* at p. 4 (at Tab 9). This agreement was acknowledged by EPA's September 22, 2010 letter (at Tab 10).

and EPA has no basis for determining that the LWG is in violation of the Consent Order for failing to make revisions to the BHHRA that EPA has not previously requested, particularly in light of EPA's statement in July 2010 that it was providing a "complete set of comments" on the BHHRA and "clear direction on the specific revisions" necessary to resolve those comments. EPA's determination of noncompliance cannot be sustained on the basis of an alleged "deficiency" that relates to a brand-new issue.

Similarly, EPA's fourth identified "deficiency" in the BHHRA is that "EPA had to extensively modify the report to make the report understandable to the general public." Again, this is a completely new comment. We note, however, that, in July 2010, EPA provided 25 individual comments on the executive summary to the BHHRA.[10] The LWG made detailed revisions to the executive summary consistent with the agreed resolution of these comments, and EPA has now deleted the entire executive summary. EPA has also deleted the conclusions of the draft final BHHRA, which the LWG modified extensively to address EPA's July 2010 comments. It is difficult for us to see how removing the executive summary and the conclusions from the BHHRA serve to make the report "understandable to the general public," and EPA's June 22 edits are themselves inconsistent with the agreed resolution of EPA's "complete set of comments" on the BHHRA. If EPA felt the LWG's initial BHHRA draft was not understandable to the general public, the LWG should have been able to assume any changes EPA thought were necessary to make it understandable would have been included in EPA's "complete comments" to that draft, not that EPA would feel the need to make new revisions in the final BHHRA to text that it did not even comment on in the first draft.

The June 22nd letter marks a breakdown in the RI/FS process

The LWG has worked with EPA at the Portland Harbor Site for over 11 years. Although there have been disagreements, the overall tone of the working relationship has been positive. Up until now, the LWG has never formally invoked dispute resolution, preferring to work diligently and creatively with EPA's staff and management to ensure the process moves forward to the shared goal of implementing cleanups at the Site. Based on all of the work described above that had been done to resolve EPA's comments on the 2009 version of the BHHRA, and EPA's representations to the LWG over the last several months that its comments would be clarifying in nature, the LWG was surprised and disappointed in the nature of EPA's June 22 letter.

EPA's June 22 letter is an indication of a breakdown in the process. Both sides reasonably expect that if meetings are conducted and resolutions are agreed to in writing, those agreements will be honored, even if key representatives who participated in the meetings and wrote the resolutions are no longer working on the project. If EPA subsequently had questions or concerns about how comments were resolved, they should have been raised at an early point in the process, not as an unsupported assertion of noncompliance and a threat of stipulated penalties at this late date.

The cleanup and monitoring process at this Site will likely occur over an extended period of time, certainly much longer than the 11 years already spent on the RI/FS. It is reasonable to assume that new staff, managers, and representatives will be assigned to the project for EPA, its

[10] None of these 25 comments requested or directed deletion of the executive summary. *See*, July 16, 2010 EPA comments on the BHHRA, pp. 11-19 (at Tab 8).

partners, and the PRPs. The parties need to work well together to manage the inevitable disagreements that will arise on technical and legal issues. All parties involved in the cleanup process, including the members of the LWG, the dozens of additional parties that may participate in Consent Decree(s) negotiations, EPA, and EPA's partners need to have a reasonable assurance that every party will act in good faith and not renege on or disregard written resolutions of issues and disagreements.

EPA is likely aware that its assertion of noncompliance has generated several stories in the media. The LWG is serious about its responsibility to provide an RI/FS that is consistent with the National Contingency Plan and EPA national guidance, in compliance with the Consent Order, and that will support a cleanup at the Site that will protect public health and the environment. The fact that EPA's assertion of deficiencies and noncompliance is now a public issue is a significant concern to all of the members of the LWG. Rather than misstating the LWG's performance in public, the LWG strongly urges that EPA reconsider its position on the BHHRA and retract its letter. If EPA does have remaining issues or questions on the BHHRA, it should discuss and resolve those issues and questions with the LWG in accordance with the working relationship we have had to date with EPA.

EPA should retract its June 22 and June 29 letters and the directed revisions to the BHHRA

In summary, EPA's June 22 and 29 letters fail to demonstrate that the LWG has not complied with the Consent Order. EPA should retract the letters and their allegations of non-compliance immediately. EPA's directed revisions to the BHHRA are without factual support, an unexplained reversal of prior agency positions and agreements, are arbitrary and capricious, and represent a breakdown in the RI/FS process, and should be retracted as well.

Sincerely,

The Lower Willamette Group

Enclosures: Table 1: Deficiencies Identified by EPA in its June 22, 2012 Cover Letter
Table 2: General Categories of LWG Objections to the EPA June 22, 2012 Revisions
Table of Contents of Supporting Documentation
Supporting Documentation (on CD)

cc: Lori Cora, EPA Region 10 (via Federal Express)
Confederated Tribes and Bands of the Yakama Nation (via EPA Shared Server)
Confederated Tribes of the Grand Ronde Community of Oregon (via EPA Shared Server)
Confederated Tribes of Siletz Indians of Oregon (via EPA Shared Server)
Confederated Tribes of the Umatilla Indian Reservation (via EPA Shared Server)

Confederated Tribes of the Warm Springs Reservation of Oregon (via EPA Shared Server)
Nez Perce Tribe (via EPA Shared Server)
Oregon Department of Fish & Wildlife (via EPA Shared Server)
United States Fish & Wildlife (via EPA Shared Server)
Oregon Department of Environmental Quality (via EPA Shared Server)
LWG Legal
LWG Repository

Table 1: Deficiencies identified by EPA in its June 22, 2012 Cover Letter:

Issue Number	Deficiency	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
1	*"The discussion of the process used to evaluate risks to humans and the conclusions were not clearly presented and, in fact, there were several instances of incorrect or misleading information. For example, the BHHRA repeatedly stated that the exposure assessment assumed someone ate fish every day of the year for 30 years.* *The LWG is fully aware that such a statement is not accurate. Consumption rates are average lifetime intake doses mathematically averaged to give an average daily rate. EPA commented on this issue in our February 9, 2010 comment letter[1]; however, the LWG failed to address it."*	This issue was not raised by EPA during development and finalization of the Programmatic Work Plan.	On July 16, 2010, EPA provided five specific comments on text in the BHHRA (**comments S91, S96, S143, S150, and S179, discussed below as 1.a through 1.d**). EPA identified only two of these comments as a "directed change."	LWG agreed to revise all text as requested.	All text revised or deleted as requested. One instance (§6.2.5.3) of this "every day of every year" formulation of the fish consumption rate was carried through into the May 2011 draft as an oversight. EPA did not comment on this specific sentence in the 2009 draft.	
1a			July 16, 2010, **comment S91** (revise): §5.2.5, pp. 86-91: "When discussing fish consumption in the Uncertainty Section, revise the text as indicated: *"Fish consumption was assumed to occur at this level every day of every year for 70 years (or 30 years)."* Fish ingestion rates are annually amortized based on the estimated number of fish meals per month and typical serving sizes. This rate does not imply that fish is ingested every day. In fact, all ingestion for a given rate could in theory occur over a few to several months, with no fish consumption for the rest of the year. In addition, such patterns could change over the course of 30 years, and greater fish consumption could occur in some years and less in others. The assumption is that over the course of 30 years, individual fish ingestion rates don't change substantively. This comment also applies to the discussion regarding consumption of shellfish on page 91.	LWG November 18, 2010 *General Responses to EPA's Non-Directive Comment Key Issues on the BHHRA*: "The BHHRA will be revised consistent with the comment."	Text modified consistent with the comment resolution.	
1b			July 16, 2010, **comment S96 b** (directed change): §5.2.6, pp. 91-92: "Uncertainties should be discussed in Section 7, Uncertainty Analysis. Move the last paragraph in this section to the uncertainty section Modify the following sentence: *"The shellfish consumption scenario assumes the same ingestion rate every day*	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "As discussed at the September 9 meeting, the BHHRA will be revised per these directed changes."	Text modified consistent with the comment resolution.	

[1] Note that EPA's February 9, 2010 letter does not discuss this issue; EPA's comments on average consumption rates are found in the July 16, 2010 BHHRA Specific Comments table.

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Issue Number	Deficiency	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			of every year for 30 years." to note that, as stated in the comments above on fish consumption, shellfish consumption rates are annually amortized based on the estimated number of shellfish meals per month and typical serving sizes. This rate does not imply that the same amount of fish is consumed every day."			
1c			July 16, 2010, **comment S143,** §7.2.5.3, p. 121 (issue): Delete or modify this sentence as shown: "In addition to the uncertainties behind the rates of fish consumption, it was assumed that the frequency of consumption occurred at the same ingestion rate every day of every year for 30 years for the adult fisher scenarios." The reference to consuming fish or shellfish "every day of the year" is misleading, as the values for ingestion of fish and shellfish represent annualized rates. For example, the rate of 17.5 g/day is equivalent to two 8-oz meals per month. Using a daily rate is a method to simplify the risk calculations, and does not imply that fish and shellfish are consumed on a daily basis.	See comment resolution in 1a above.	"In addition to the uncertainties behind the rates of fish consumption, it was assumed that the frequency of consumption occurred at the same ingestion rate ~~every day of every year~~ for 30 years for the adult fisher scenarios."	
1d			July 16, 2010, **comment S150**, §7.2.5.3, p. 123 (directed change): Delete or revise the following sentence to clearly note that daily consumption rates represent mathematical artifacts to account for annual rates: *"Shellfish consumption was assumed to occur at the same rate every day of every year for 30 years."*	See comment resolution in 1b above.	~~"Shellfish consumption was assumed to occur at the same rate every day of every year for 30 years.~~ Daily shellfish consumption rates used in this BHHRA represent mathematical artifacts to account for annual consumption rates. The daily consumption rates for shellfish represent approximately two and a half 8-ounce meals per month (18 g/day ingestion rate), and just less than one 8-ounce meal every two months (3.3 g/day ingestion rate)."	
1e			July 16, 2010, **comment S179,** §8.1.1.1, pp. 138-139 (revise): Delete or revise the text in the third sentence and in all subsequent text in this section and Section 8.1.1.2 as indicated: *"Fish consumption was assumed to occur at the same ingestion rate, every day of every year"* The reference to consuming fish or shellfish "every day of the year" is misleading in that the fish and shellfish ingestion rates represent annual rates converted to average daily rates.	See comment resolution in 1a above.	"Fish consumption was assumed to occur at the same ingestion rate ~~, every day of every year,~~ for 30 years for an adult and for 6 years for a child." "Shellfish consumption was assumed to occur at the same ingestion rate~~, every day of every year,~~ for 30 years."	
2a	*"There were several instances where the BHHRA does not fully reflect EPA's directions for change, directions given years before and reiterated in our comments to previous versions.*	§3.4.3.1, p. 25-26. "Replicate composite samples were collected for each fishing zone for carp, crappie, and bullhead and at three of the eight river mile stations for bass. The replicate composite samples will be averaged	July 16, 2010, **comment S52** §3.4, p. 31 (clarify): "In this section and subsequently throughout the risk assessment, replace the term "95% UCL/max EPC" with "RME EPC." The repeated references to a "mean" EPC relative to one based on a 95 percent UCL	LWG November 18, 2010 *General Responses to EPA's Non-Directive Comment Key Issues on the BHHRA*: "The EPCs will be described in a factual manner in the BHHRA (i.e., the EPC will be identified as the mean, 95% UCL, or	Revised text §3.4. ~~"The EPCs used in this BHHRA incorporate CT and RME methods, consistent with EPA guidance. Because the RME scenarios in this BHHRA use either the maximum detected concentration or the 95% upper confidence limit (95% UCL) on the~~	"EPCs for RME evaluations represent either the 95 percent UCL, or the maximum detected value when either there was insufficient data to calculate a UCL or the calculated UCL was greater than the maximum reported

Table 1: Deficiencies identified by EPA in its June 22, 2012 Cover Letter:

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	For example, EPA's February 2010[2] comment on Section 3.4, page 31 was: *"In this section and subsequently throughout the risk assessment, replace the term "95% UCL/max EPC" with "RME EPC." The repeated references to a "mean"* *EPC relative to one based on a 95 percent UCL or maximum concentration is misleading. The text in the second paragraph incorrectly states that exposure point concentrations would be calculated differently for central tendency (CTE) and reasonable maximum (RME) exposures. Consistent with EPA guidance (1992,2000), the EPC should represent an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling data. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent UCL of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated. The average concentration, defined as the 95 percent UCL, should be used for both CTE and RME evaluations. The RME evaluation should be distinguished from CTE by accounting for variability in such variables as exposure frequency and intake rates."* *However, the LWG did not make the change, claiming that the EPCs were described in a factual manner. Use of the term 95% UCL/Max Scenario is incorrect and needs to be changed throughout the document. RME*	and the arithmetic mean concentrations will be used as EPCs for individual sampling locations. To address potential variation in tissue concentrations, the maximum composite results for each fishing zone and at the three river mile segments will also be used as EPCs for individual sampling locations. The uncertainty associated with using the average and maximum concentrations as EPCs will be discussed in the risk assessment. At the one-mile river mile stations where replicate composite samples were not collected for bass, the results of the single composite sample will be used as EPCs for these stations. Site-wide tissue EPCs will also be estimated using mean concentrations and 95 percent upper confidence limit (UCL) on the average or maximum composite results. Where sufficient data are available, the 95% UCLs will be calculated using an approach agreed to by the LWG and EPA and its partners, and the 95% UCLs will be used as site-wide EPCs. If sufficient data are not available, the maximum composite results will be used as site-wide EPCs. In addition, the arithmetic mean of individual sampling location EPCs will be used as site-wide EPCs."	or maximum concentration is misleading. The text in the second paragraph incorrectly states that exposure point concentrations would be calculated differently for central tendency (CTE) and reasonable maximum (RME) exposures. Consistent with EPA guidance (1992, 2000), the EPC should represent an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling data. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent UCL of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated. The average concentration, defined as the 95 percent UCL, should be used for both CTE and RME evaluations. The RME evaluation should be distinguished from CTE by accounting for variability in such variables as exposure frequency and intake rates."	maximum). The terms RME and CT will not be used in reference to the EPCs." "EPA will not require the addition of beach user exposure to groundwater seeps, use of the 95% UCL/maximum concentration for all exposure scenarios, or new child receptors." EPA December 8, 2010 *EPA General Responses to EPA Non-Directed RI, BHHRA and BERA Comments*: "EPA has reviewed the LWG responses, as summarized in the tables, and has determined that the vast majority of issues associated with addressing EPA's comments have been resolved. However, there were three comments for which the LWG did not agree to make the specified changes." Includes three unrelated comments and additional unrelated clarifications.	~~arithmetic mean as the EPC for an exposure area, this BHHRA uses the term "95% UCL/max" to reference RME EPCs, and "mean" to reference CT EPCs.~~ EPCs were calculated for the 95% upper confidence limit on the arithmetic mean (95% UCL) and the arithmetic mean for each exposure area. In some exposure areas, the maximum concentration was used instead of the 95% UCL. Therefore, the EPCs are referred to as the 95% UCL/max and mean throughout this BHHRA."	value. Although inconsistent with EPA guidance (EPA 1992), EPCs for sediment and surface water CT evaluations were calculated as the simple arithmetic mean. EPCs for fish/shellfish consumption scenarios are the lesser of the 95 percent UCL or the maximum detected concentration, central tendency evaluations were achieved by using mean or median consumption rates."

[2] See note 1.

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	and CT are not defined based solely on calculation of EPC. Actually, EPC should be the same for both the RME and CT. Since *the LWG used different EPCs for the RME and CT calculations, EPA is requiring the removal of the CT evaluations for the consumption scenarios in the BHHRA."*					
2b	*"Further, reference to RME and CT in the BHHRA were not consistent with those agreed to in the Programmatic Work Plan. EPA has modified the BHHRA to reflect those agreements and adequately describe the RME and CT."*	§3.4.3, p. 25. "The fish consumption evaluation will be based on a range of fish consumption rates. Because these consumption rates will not be designated as representing either RME or CT exposures, the EPCs for tissue will not be developed specifically for RME or CT scenarios." §3.5.1.4, p. 32. "Site-specific fish consumption information is not available for the recreational fisher or high consumption non-tribal fisher scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist for these receptors, 3 ingestion rates will be used to calculate intakes for adults and 3 will be used for children. For adults, the fish ingestion rates that will be used in the HHRA are 17.5 grams per day (g/day), 73 g/day, and 142 g/day. The corresponding rates that will be used for children are 7 g/day, 31 g/day, and 60 g/day. These ingestion rates are anticipated to represent average to high end ranges of fish consumption for these receptors."	There were 10 comments provided on July 16, 2010 that requested or directed revisions to text describing the fish consumption scenarios. None of those comments referenced RME or CT scenarios. For example, July 16, 2010, **comment G1** (directed change): "The draft Portland Harbor Baseline Human Health Risk Assessment (BHHRA) includes numerous statements regarding the fish consumption rates used to evaluate the risks to human health. The three primary non-tribal fish ingestion rates used in the draft BHHRA are characterized as high (17.5 grams per day [g/day]), higher (73 g/day), and highest (142 g/day). EPA disagrees with this characterization, believes them to be misleading, and believes that significantly higher ingestion rates may be appropriate to represent different local and ethnic populations that rely on fishing as part of their culture and/or as a substantial food source. As such, the three ingestion rates presented in the BHHRA should be characterized as low, moderate, and high. The rate of 17.5 g/day (equivalent to two 8-ounce meals per month) is based on the 90th percentile rate for uncooked freshwater and estuarine finfish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002b, data from USDA CSFII Study). The 90th percentile for fish consumers only from this USDA study is much higher, at 200 g/day. EPA uses the 17.5 g/day rate to approximate a fish-consuming population that does not include tribal or subsistence fishers. It is not an unreasonable rate, and should not be referred to as a high ingestion rate, but rather as a low ingestion rate. A non-tribal adult fish consumption rate of 73 g/day was used in this risk assessment based on data from the Columbia Slough. The possible uncertainties associated with the consumption rates derived from this study are appropriately discussed in the	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "As discussed at the September 9th meeting, ingestion rates will be presented in the revised BHHRA as the numeric rates (i.e., grams per day or meals per month) and the source of the rates will be presented, consistent with the text in the Programmatic Work Plan. Characterization or descriptors of the ingestion rate (e.g., "low", "high") will not be included in the revised BHHRA." EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments*: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.	Revised text in §3.5.1.5.3: "The fish consumption scenario included three different fish ingestion rates, as well as single species and multiple species diets of resident fish species. Study Area-specific fish consumption information is not available for the fish consumption scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist, three ~~high-end~~ ingestion rates were used to calculate intakes for adults and three were used for children. EPA specified the ingestion rates used in this BHHRA. For adults, the fish ingestion rates were 17.5 grams per day (g/day), 73 g/day, and 142 g/day. These rates correspond to approximately 2 meals per month, 10 meals per month, and 19 meals per month, based on an 8-ounce serving size, every month of the year, consisting exclusively of fish caught within the Study Area. It should be noted that the current fish consumption advisory, based on PCBs, for the LWR recommends that children and expectant mothers do not eat resident fish from the Portland Harbor, and that healthy adults eat no more than one 8-ounce meal per month of resident fish from the Portland Harbor (ODHS 2007). However, it is unclear to what extent this advisory is followed by people who consume fish from the Study Area."	"No studies were located that document specific consumption rates of recreational or subsistence anglers in Portland Harbor prior to its listing as a Superfund site. Surveys conducted subsequent to the listing would not be representative of historical, baseline consumption patterns due to subsequent fish advisories and efforts to limit consumption of fish caught from the harbor. Therefore, fish consumption rates from published studies were used to describe the range of reasonably expected exposures relevant to the different populations known to occur in the Portland Harbor area. Three different rates were evaluated: 17.5 grams per day (approximately 2 eight ounce meals per month), 73 g/ day (10 eight ounce meals per month), and 142 g/day per day (19 eight ounce meals per month). The term "recreational fishers" is intended to encompass a range of the population while focusing on those who may fish on a more-or-less regular basis, and "subsistence fishers" to represent populations with high fish consumption rates, recognizing that fish are not an exclusive source of protein in their diet. Accordingly, 17.5 g/day is considered representative of a CT value for recreational fishers, and 73 g/day was selected as the RME value representing the higher-end consumption practices of recreational fishers. The consumption rate of 142 g/day represents a RME value for high fish consuming, or subsistence, fishers. No CT value was selected because the evaluations based on 17.5 g/day and 73 g/day inform the risks associated with lower consumption rates. Consumption rates for children aged 6 years and younger were calculated by assuming that their rate of fish consumption is

Table 1: Deficiencies identified by EPA in its June 22, 2012 Cover Letter:

Issue Number	Deficiency	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			BHHRA. The BHHRA discussion and the data from the USDA study support use of a fish consumption value of 73 g/day as moderate consumption rate, not a higher consumption rate. The rate of 142 g/day used as the highest rate for non-tribal fishers in the draft BHHRA is the 99th percentile for consumers and non-consumers from the same USDA study; the consumption rate for consumers only from this study is 506 g/day. The ingestion rate of 142 g/day is used by EPA in developing Ambient Water Quality Criteria (AWQC) for consumers who obtain much of their daily protein from fish. The consumption rate of 142 g/person/day was selected in the BHHRA to represent high-frequency, non-tribal fishers, and represents an appropriate "high" ingestion rate for the Portland Harbor (PH) risk assessment." See also July 16, 2010, **comments S49, S63, S64, S93, S94, S98, S101, S138, and S140**			approximately 42 percent of an adult, based on the ratio of child-to-adult consumption rates presented in the CRITFC Fish Consumption Survey (CRITFC 1994). The corresponding rates that were used for children are 7 g/day, 31 g/day, and 60 g/day." .
3	*"There were many instances in the BHHRA where the only explanation the LWG provides for why something is done was that EPA directed or otherwise required it be done. While it may be true EPA directed changes, the LWG is fully aware of the technical basis for the direction and should have included such technical basis in the report. The LWG's failure to fully explain the basis for how the risk assessment was done is not consistent with EPA guidance nor is the report complete and transparent without it. Therefore, EPA had to modify the report to provide the rational for the directions in the text of the BHHRA for clarity and relevance for the assessment."*	This issue was not raised by EPA during development and finalization of the Programmatic Work Plan.	EPA did not provide any comments on the 2009 Draft BHHRA indicating that the rationale for EPA's directions needed to be provided. Several of the July 16, 2010 comments request or direct deletion of specific text indicating that an assumption or evaluation was directed or required by EPA. For example, **comment S125**, §7.2.3, p. 115 (directed change): Delete the following sentences: ~~*"As required by EPA Region 10, this BHHRA included exposure scenarios that are not well documented, so it is unknown to what extent exposures currently occur, if at all, within the Study Area. In addition, this BHHRA evaluated risks associated with a hypothetical future scenario, which is not anticipated to reasonably occur in the future based on current information for the Study Area. The uncertainties associated with these potential and hypothetical exposure scenarios are discussed in the following subsections."*~~ Consistent with EPA Superfund guidance, EPA and its partners chose only those scenarios that are reasonably anticipated to occur and are consistent with current statutory or regulatory requirements (e.g. designated beneficial use of the river as a source for drinking water).	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "The LWG disagrees with EPA's directed changes requiring the deletion of references to prior EPA direction from the draft BHHRA. As discussed at the August 20th and September 9th meetings, language stating that evaluations were done at the direction of EPA can remain in the revised BHHRA. Language implying opinion or judgment about the prudence of that direction will be removed." EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments*: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.	Revised text in §7.2.3 (now §6.2.3): "Some of the exposure scenarios evaluated in this BHHRA have limited documentation regarding the actual extent of exposure to receptors in the Portland Harbor. These scenarios were included in this BHHRA at the direction of EPA Region 10. The uncertainties associated with these scenarios are discussed in the following subsections. ~~As required by EPA Region 10, this BHHRA included exposure scenarios that are not well documented, so it is unknown to what extent exposures currently occur, if at all, within the Study Area. In addition, this BHHRA evaluated risks associated with a hypothetical future scenario, which is not anticipated to reasonably occur in the future based on current information for the Study Area. The uncertainties associated with these potential and hypothetical exposure scenarios are discussed in the following subsections.~~"	All references to EPA directing the use of specific scenarios, assumptions or evaluations in the BHHRA have been deleted. For example, the text addressed by EPA's June 16, 2010 **S125** (now §6.2.2), has been revised to read, "Some of the uncertainties associated with the exposure scenarios evaluated in the BHHRA are discussed in the following subsections."
4	*"Overall, the BHHRA did not present the process and information in a clear and*	This issue was not raised by EPA during development and finalization of the Programmatic Work Plan.	EPA did not provide any comments on the 2009 Draft BHHRA indicating that the process or information was not presented in			This is a new comment from EPA, and is reflected in extensive text revisions throughout EPA's redline/strikeout

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	transparent manner that would allow anyone outside those intimately involved in the development of this assessment to follow and understand. Thus, EPA had to extensively modify the report to make the report understandable to the general public."		a clear and transparent manner. Note EPA December 23, 2009 *Preliminary Comments on the Baseline Human Health and Ecological Risk Assessments*: "Overall, most of the procedures followed in the BHHRA and BERA are consistent with and followed the procedures agreed upon by EPA and the LWG for completing the baseline risk assessments." See also, EPA July 16, 2010 *EPA Comments on Portland Harbor draft Remedial Investigation Report*: "EPA has attempted to provide clear direction on the specific revisions that are needed to resolve the comments" on the baseline risk assessments.			edits.

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
1a	**The LWG objects to EPA's revisions that delete factual information regarding clam consumption because these revisions are inconsistent with prior agreements between EPA and the LWG.**	This scenario was not included in the Programmatic Work Plan. The scenario was added to the BHHRA per EPA's Identification of Round 3 Data Gaps (December 2, 2005).	July 16, 2010, **comment G2** (note): "The fact that collection of *Corbicula* is illegal is relevant but not particularly important for the pathway in general. Indications are that *Corbicula* are being collected and consumed to some extent (e.g., from the Linnton Community Center's discussion with transients). It is reasonable to assume that bivalve consumption is a current and potential future exposure pathway and that future biomass would increase. Therefore, the low clam mass that may limit current bivalve consumption does not apply to future exposure."	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "As discussed at the August 20th and September 9th meetings, the clam consumption scenario can be factually discussed in the revised BHHRA. Language regarding the evaluation of shellfish consumption at the direction of EPA and that the harvest and possession of Asian clams is illegal can remain in the revised BHHRA. Information from the Linnton study will be cited as such. Language implying opinion or judgment about the clam consumption scenario will not be included in the revised BHHRA." EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments*: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.	Text modified consistent with the comment resolution and related specific comments listed below.	EPA deleted or modified text that was specifically agreed-upon in the 2010 comment resolution process.
1b			EPA's comments on the 2009 Draft BHHRA did not include comments on §3.3.6.		Text in §3.3.6. "Like fish, shellfish may bioaccumulate certain chemicals in their tissue. Populations that consume shellfish may be exposed to COPCs that accumulate in the shellfish tissue. In the Programmatic Work Plan, crayfish was identified as the species to use to evaluate shellfish consumption. Additionally, as required by EPA, consumption of clams is also evaluated in this BHHRA. Harvest and possession of Asian clams, which is the clam species that was found in the LWR during sampling events, is illegal in the State of Oregon because Asian clams are on the prohibited species list of the ODFW rules regarding the importation, possession, confinement, transportation and sale of nonnative wildlife (OAR 635–056–0050)."	"Certain contaminants can bioaccumulate in shellfish, and populations may be exposed to COPCs through consumption of shellfish that are collected within the Study Area."
1c			July 16, 2010, **comment S51** §3.3.6.1, p. 40 (revise): "The language in this section should be deleted and replaced with the following text: *"Although the extent of shellfish consumption in the lower Willamette River is not known, information regarding the consumption of shellfish in the lower Willamette River is available. The Oregon Office of Environmental Public Health, Department of Health Services (DHS) had*	LWG November 18, 2010 *General Responses to EPA's Non-Directive Comment Key Issues on the BHHRA*: "This issue was addressed in the responses to EPA's Directive Comments." EPA December 8, 2010 *EPA General Responses to EPA Non-Directed RI, BHHRA and BERA Comments*: "EPA	Revised text in §3.3.6.1. "In theory, shellfish consumption could occur throughout the Study Area wherever shellfish are found. However, it is not known to what extent shellfish consumption occurs~~, as there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area~~. The Linnton Community Center project (Wagner 2004) reported that some transients	"Certain contaminants can bioaccumulate in shellfish, and populations may be exposed to COPCs through consumption of shellfish that are collected within the Study Area. The actual extent shellfish harvesting and consumption is presently occurring is not known. The Linnton Community Center project (Wagner 2004) reported that some transients reported eating clams and

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			previously received information from ODFW indicating that an average of 4300 lbs of crayfish were commercially harvested from the portion of the Willamette River within Multnomah County each of the 5 years from 1997-2001. Most of this catch was sold to the Pacific Seafood Company of Oregon. DHS also has information from local commercial crayfish harvesters indicating that Europe is a major portion of their market. Furthermore, as part of the McCormick and Baxter assessment in 1991, Ken Kauffman at DHS talked with the wife of a licensed commercial crayfish harvester who served (at that time) as the secretary-treasurer of the Oregon Crayfish Association. She indicated that the area around McCormick and Baxter was a very productive Cray fishery and that she and her husband had harvested there prior to the advisory on many occasions. *"In addition to this historical commercial crayfish harvesting information in the Lower Willamette, DHS also occasionally receives calls from citizens interested in harvesting crayfish from local waters who are interested in fish advisory information. Between 2001 and 2007, DHS fielded 8 calls from citizens who reported catching and eating crayfish from Portland-area waters, although only one was specifically from the Study Are). It is not known what percent of individuals who catch and eat crayfish contact DHS to ask for fish advisory information. DHS estimates that for each person who contacts them regarding the safety of consuming crayfish from the Lower Willamette, there are many more that catch and consume the animals without contacting DHS* *"Although the collection of Corbicula is illegal, this is not particularly important for the pathway in general. There are indications that Corbicula are being collected and consumed (e.g., from the Linnton Community Center's discussion with transients). It is reasonable to assume that bivalve consumption is a current and possible future exposure pathway and that future biomass would increase.""*	has reviewed the LWG responses, as summarized in the tables, and has determined that the vast majority of issues associated with addressing EPA's comments have been resolved. However, there were three comments for which the LWG did not agree to make the specified changes." Includes three unrelated comments and additional unrelated clarifications.	reported eating clams and crayfish; however, many of the individuals indicated that they were in the area temporarily, move from location to location frequently, or have variable diets based on what is easily available. The Superfund Health Investigation and Education (SHINE) program in the Oregon Department of Human Services (DHS) stated that is unknown whether or not crayfish are harvested commercially within Portland Harbor (ATSDR 2006). ~~In addition,~~ ODFW has records for crayfish collection in the Columbia and Willamette Rivers, but these records do not indicate whether the collection actually occurs within the Study Area. Based on ODFW's data for 2005 to 2007, no commercial crayfish landings were reported for the Willamette River in Multnomah County. DHS had previously received information from ODFW indicating that an average of 4300 pounds of crayfish were harvested commercially from the portion of the Willamette River within Multnomah County each of the five years from 1997-2001. In addition to this historical commercial crayfish harvesting, DHS occasionally receives calls from citizens who are interested in harvesting crayfish from local waters who are interested in fish advisory information. According to a member of the Oregon Bass and Panfish club, crayfish traps are placed in the Portland Harbor Superfund Site boundaries and collected for bait and possibly consumption (ATSDR 2006). Even if collection does occur within the Study Area, it is not known whether those crayfish are consumed by humans or used as bait."	crayfish, although many of the individuals indicated that they were in the area temporarily, move from location to location frequently, or have variable diets based on what is easily available. The Superfund Health Investigation and Education (SHINE) program in the Oregon Department of Human Services (DHS) stated that is unknown whether or not crayfish are harvested commercially within Portland Harbor (ATSDR 2006). ODFW has records for crayfish collection in the Columbia and Willamette Rivers, but these records do not indicate whether the collection actually occurs within the Study Area. Based on ODFW's data for 2005 to 2007, no commercial crayfish landings were reported for the Willamette River in Multnomah County. DHS had previously received information from ODFW indicating that an average of 4,300 pounds of crayfish were harvested commercially from the portion of the Willamette River within Multnomah County each of the five years from 1997-2001. In addition, DHS occasionally receives calls from citizens who are interested in harvesting crayfish from local waters and are interested in fish advisory information. According to a member of the Oregon Bass and Panfish club, traps are placed in the Portland Harbor Superfund Site boundaries and crayfish collected for bait and possibly for consumption (ATSDR 2006). Although consumption of shellfish was considered a potentially complete pathway for dockside workers, in-water workers, recreational beach users, divers, and recreational fishers, it was quantitatively evaluated only for subsistence fishers, as they were considered the most likely population to regularly harvest and consume shellfish."
1d			July 16, 2010, **comment S96** §5.2.6, pp. 91-92 (b) (directed change): "When consumption of shellfish is discussed in the Uncertainty Section, the following phrase should be deleted: *"despite the fact that there is no documented ongoing consumption of shellfish in the Study Area and the harvest*	See comment resolution in 1a above.	Deleted text from §5.2.6, p. 121. "~~despite the fact that there is no documented ongoing consumption of shellfish in the Study Area and the harvest or possession of Asian clams, the species assessed in the BHHRA, is illegal.~~"	

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			or possession of Asian clams, the species assessed in the BHHRA, is illegal.""			
1e			July 16, 2010, **comment S126** §7.2.3.1, pp. 115-116 (directed change): The following sentence in the first paragraph should be deleted: "~~*However, there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area, and the harvest or possession of Asian clams, which is the species assessed in this BHHRA, is illegal.*~~"	See comment resolution in 1a above.	Revised text in §7.2.3.1 (now §6.2.3.2): "This BHHRA evaluated risks from shellfish consumption based on crayfish and clam tissue data. However, ~~there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area, and~~ the harvest or possession of Asian clams, which is the species assessed in this BHHRA, is illegal."	All text deleted.
1f			July 16, 2010, **comment S147** §7.2.5.3, p. 122 (directed change): "Revise the text in the second paragraph following the bulleted list as indicated: "*However, it is not known to what extent shellfish consumption occurs~~, as there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area~~.*""	See comment resolution in 1a above.	Revised text in §7.2.5.3 (now §6.2.5.3): "The information suggesting that shellfish consumption may occur at the Study Area comes from a community project sponsored by the Linnton Community Center, as discussed in Section 3.3.6. However, it is not known to what extent shellfish consumption occurs~~, as there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area~~."	"Information regarding consumption of shellfish from the Study Area relies in part from information obtained from a community project sponsored by the Linnton Community Center, as discussed in Section 3.3.6. However, it is not known to what extent shellfish consumption actually occurs."
1g			July 16, 2010, **comment S182** §8.1.1.2, p. 139 (revise): "Revise the first sentence as follows: "~~*It is not known to what extent*~~ *Current and potential future shellfish consumption rates for the site are not known.* ~~*actually occurs, and there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area.*~~""	See comment resolution in 1c above.	Revised text in §8.1.1.2 (now §7.1.1.2): "~~It is not known to what extent shellfish consumption actually occurs, and there is no documentation of ongoing shellfish consumption by humans occurring in the Study Area.~~ Current and potential future shellfish consumption rates for the site are not known."	Section deleted.
2a	**The LWG objects to EPA's revisions describing the drinking water scenario, including deleting the term "hypothetical", because these revisions are inconsistent with prior agreements between EPA and the LWG.**	This scenario was not included in the Programmatic Work Plan. The scenario was added to the BHHRA per EPA's Identification of Round 3 Data Gaps (December 2, 2005).	July 16, 2010, **comment G6** (directed change): "Much of the language in the draft BHHRA that discusses the Willamette River as a potential future drinking water source is inappropriate. Under OAR 340-041-0340, Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. CERCLA sets out a mandate for remedies that are protective for both private and public users of surface water or groundwater. The Willamette River is potable and capable of serving as a potential drinking water source; thus, the expectation is that this resource will be protected and remediated to achieve such use (40 CFR 300.430(a)(1)(ii)(F)). This expectation is reflected in the current remedial action objectives and ARARs for the PH site and must be reflected in the HHRA for the site. Throughout the draft HHRA, where reference is made to the risk characterization done for potential future domestic use of surface water, much of the language will need to be deleted and/or modified to be consistent with the fact that surface water is potable and capable of serving as a potential drinking water source and that the expectation is that the resource	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA*: "As discussed at the August 20th and September 9th meetings, the term "hypothetical" can be used when describing the use of the Lower Willamette River (LWR) as a domestic water source, as long as factual information is provided to support that characterization. Language regarding the designated beneficial use of the LWR and the need to protect the resource will be included in the revised BHHRA. Language regarding the need to remediate the resource will not be included. The following language is an example of how the scenario will be described in the revised BHHRA: "*Even though no current or future uses of the LWR within Portland Harbor as a domestic water source have been identified, as discussed above under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. Because the Willamette River is capable of serving as a potential drinking water*	Text modified consistent with the comment resolution and related specific comments listed below.	EPA deleted or modified text that was specifically agreed-upon in the 2010 comment resolution process.

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			will be protected and remediated to achieve such use. EPA has provided comments on this inappropriate language which occurs throughout the draft BHHRA."	*source, the expectation is that this resource will be protected to achieve such use with adequate pretreatment.""* EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments*: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.		
2b			July 16, 2010, **comment S36** §2.3.4, p. 26 (directed change): "Replace "Hypothetical" with "Potential" in the title for this section. 1st paragraph- Add the following sentence: *"Even though no current or future uses of the LWR within Portland Harbor as a domestic water source have been identified, as discussed above under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. Because the Willamette River is potable and capable of serving as a potential drinking water source, the expectation is that this resource will be protected and remediated to achieve such use (40 CFR 00.430(a)(1)(ii)(F)) under CERCLA.""*	See comment resolution in 2a above.	Revised text in §2.3.4. "Even though no current or future uses of the LWR within Portland Harbor as a domestic water source have been identified, under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. Because the Willamette River is capable of serving as a potential drinking water source, the expectation is that this resource will be protected to achieve such use with adequate pretreatment. Although surface water within the Study Area is not currently used as a domestic water source, nor are there future plans for domestic water use within the Study Area, surface water data were quantitatively evaluated in the BHHRA as a hypothetical future domestic water source at the direction of EPA (see Section 2.4.5 below). The same criteria and screening values used for data to assess direct contact with surface water and the groundwater seep were used to select COPCs for surface water as a hypothetical future domestic water source. As with the surface water and groundwater seep screening, the noncarcinogen RSLs were divided by 10 to account for potential multiplicative effects, and the modified RSLs were used as the screening values."	Section deleted.
2c			July 16, 2010, **comment S41** §2.4.5, pp. 29-30 (directed change): "Delete "Hypothetical" from the title and from the first and second sentences on page 30, The word "hypothetical" should be deleted throughout the BHHRA when referring to SW for domestic use. Note that "future" implies by itself something that is "hypothetical," "potential," "possible," etc. 1st Paragraph - As stated in General Comment 5, under OAR 340-041-0340, Table 340A, domestic water supply is a designated beneficial use of the Willamette	See comment resolution in 2a above.	Revised text in §2.4.5."There is no known current or anticipated future use of surface water within the Study Area for a drinking water supply. Even though no current or future uses of the LWR within Portland Harbor as a domestic water source have been identified, under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. Because the Willamette River is capable of serving as a potential drinking water source, the expectation is that this resource will be	Section deleted.

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			River, with adequate pretreatment, and the surface water is potable and capable of serving as a potential drinking water source. Therefore, the first paragraph in this section should be deleted. Uncertainties associated with future use of surface water can be included in the Uncertainty section. Section 2.4.5 should also include a brief discussion of the sources of surface water contaminants. Although EPA agreed that "integrated data" could be used to select COPCs and develop EPCs for surface water as a drinking water source, it was assumed that surface water data from throughout the Portland Harbor site that could be integrated (i.e., by combining near bottom and near surface samples in a given location) would be used and that these data would be integrated as appropriate. Instead only surface water data from the river transects, Willamette Cove, Cathedral Park and the Shipyard were used. Water could be withdrawn from the river at any point for use as drinking water. Therefore, the COPC screening for this pathway should be revised using all appropriate data sets, including data from Round 3. See additional comments on Section 3.4.3.4."		protected to achieve such use with adequate pretreatment. Potential sources of contaminants to surface water are discussed in the RI. ~~Even in the unlikely event that surface water in the Study Area were to be used for a domestic water supply, which includes drinking and bathing, such use would be subject to requirements for adequate pretreatment in accordance with the Safe Drinking Water Act, and Oregon rules. However, for this BHHRA, EPA required assessment of domestic uses of untreated surface water from the Study Area.~~ Because future use of the LWR as a domestic water supply would require adequate pretreatment, the evaluation of untreated surface water as a drinking water source is designated a hypothetical scenario. The inclusion of the assessment of domestic use of untreated surface water from the Study Area was done at the direction of EPA."	
2d			July 16, 2010, **comment S43** §3.1, p. 31 (directed change): "The difference between a "potentially exposed" and "hypothetically exposed" population is not clear. In the first sentence here and throughout the risk assessment, delete the term "hypothetical" when discussing potential exposure pathways."	See comment resolution in 2a above.	No change to text.	"Potentially exposed populations were identified based on consideration of current and potential future uses of the Study Area."
2e			July 16, 2010, **comment S44** §3.2, p. 33 (directed change): "In the bulleted list continued from page 32, replace "Hypothetical domestic water use" with "residents" or a similar term. "Domestic water use" is an exposure pathway, not a current or potentially exposed concentration. In addition, The CSM in Figure 3-1 should delete "Hypothetical" for residential ingestion of surface water. As previously indicated, future is a sufficient caveat."	See comment resolution in 2a above.	Revised text in §2.4.5."~~Hypothetical~~ dDomestic water user"	
2f			July 16, 2010, **comment S48** §3.3.3.4, p. 38 (directed change):" Delete "Hypothetical" in the title for this section. The text in this section should be modified to be consistent with the comments in General Comment 5 and on Section 2.4.5, as follows: *"As mentioned in Section 2.4.5, no known current ~~or anticipated future~~ use of surface water within the Study Area for a domestic*	See comment resolution in 2a above.	Title change: "~~Hypothetical Future~~ Domestic Water User" Revised text in §3.3.3.4. "As mentioned in Section 2.4.5, there is no known ~~or anticipated future~~ current use of surface water within the Study Area for a domestic water supply. ~~Due to a requirement by EPA~~ However, because domestic water use is a designated beneficial use of the Willamette River following adequate pretreatment, ~~river water,~~ the ~~hypothetical~~ use	Section deleted.

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			water supply is known or planned. However, ~~Due to a requirement by EPA, the hypothetical~~ because domestic water use is a designated beneficial use of the Willamette River, ~~a use of untreated~~ river water as a domestic water source was assessed as a ~~hypothetical~~ future pathway for both adult and child residents, resulting in exposures through ingestion and dermal contact. In this scenario, exposure to surface water could ~~hypothetically~~ potentially occur throughout the Study Area.""		of untreated river water as a domestic water source was assessed as a hypothetical future pathway for both adult and child residents, at the direction of EPA, ~~resulting in exposures through ingestion and dermal contact.~~ In this scenario, exposure to untreated surface water could hypothetically occur from ingestion and dermal contact throughout the Study Area. At the direction of the EPA, volatilization of chemicals from untreated surface water to indoor air through household uses was identified as a potentially complete exposure pathway for hypothetical future domestic water use."	
2g			July 16, 2010, **comment S56** §3.4.3.4, p. 48 (directed change): "Delete "Hypothetical" in the title for this section."	See comment resolution in 2a above.	Title change: "~~Hypothetical Future~~ Domestic Water User"	
2h			July 16, 2010, **comment S68** §3.5.1.8, p. 59 (directed change): "Title - Replace "Hypothetical" with "Potential" in the title for this section. Change the word "hypothetical" to "potential" when referring to domestic water in this section and throughout the HHRA. Inhalation of contaminants from surface water should be included as a part of the scenario, unless it can be shown that this is not an issue for the surface water contaminants that are selected for evaluation in Section 6."	See comment resolution in 2a above.	Title change: "~~Hypothetical~~ Domestic Water Users" Revised text in §3.5.1.8. "~~Although s~~ Surface water within the Study Area is not currently used as a domestic water source and there are no known plans to use it as a domestic water source in the future. However, the designated beneficial uses of the Willamette River include domestic water supply, assuming adequate pretreatment of the water prior to consumption. EPA specified that the BHHRA evaluate use of untreated river water as a domestic water supply. This scenario is considered hypothetical because pretreatment of surface water for domestic use would be required under current state laws."	Paragraph deleted.
2i			July 16, 2010, **comment S85** §5.2.3.4, p. 83 (directed change): "Replace "Hypothetical" with "Potential" in the title for this section and elsewhere within Section 5.2.3. As previously discussed, additional surface water sampling data should be used for the screening for selection of COPCs, using both MCLs and EPA RSLs."	See comment resolution in 2a above.	Title change: "~~Hypothetical~~ Domestic Water User" Revised text in §5.2.3.4. "There is no known or anticipated future use of surface water within the Study Area for a domestic water supply. Because the designated beneficial use of the Willamette River is as a domestic water supply with adequate pretreatment~~However~~, ~~at~~ EPA ~~'s direction, untreated~~ directed that surface water ~~was be~~ evaluated as a ~~hypothetical~~ future domestic water source for both adult and child residents. For purposes of this BHHRA, untreated surface water was used to assess risks from future domestic water uses, so the risks are considered hypothetical."	Paragraph deleted.
2j			July 16, 2010, **comment S128** §7.2.3.3, p. 116 (directed change): "Replace "*Hypothetical*" with "*Potential Future*" in the title for this section. As described in General Comment 6, under OAR 340-041-0340, Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate	See comment resolution in 2a above.	Title change: "~~Hypothetical~~ Domestic Water Users" Revised text in §7.2.3.3 (now §6.2.3.4). "The domestic water user risks are based on the hypothetical use of untreated surface water drawn from the Study Area as a domestic water source. Surface water in the	"The evaluation of surface water as a domestic water source is based on the assumption that surface water is drawn from the Study Area. Within the Study Area, the LWR is not currently used as a domestic water source. According to the City of Portland, the primary domestic water source for

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			pretreatment. CERCLA sets out a mandate for remedies that are protective for both private and public users of surface or groundwater. Surface water is potable and capable of serving as a potential drinking water source; thus, the expectation is that the resources will be protected and remediated to achieve such use (40 CFR 300.430(a)(1)(ii)(F)) in the absence of pretreatment. Therefore, the text in this section should be revised as indicated:" *Surface water in the LWR within the Study Area is not currently used as a domestic water source~~, nor are there plans to use surface water within the Study Area as a domestic water source in the future~~. According to the City of Portland, the primary domestic water source for Portland is the Bull Run watershed, which is supplemented by a groundwater supply from the Columbia South Shore Well Field (City of Portland 2008). ~~In addition, the Willamette River was determined not to be a viable water source for future water demands through 2030 (City of Portland 2008)~~. Under OAR 340-041-0340, Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. CERCLA sets out a mandate for remedies that are protective for both private and public users of surface or groundwater. Willamette River surface water is potable and capable of serving as a potential drinking water source; thus, the expectation is that the resources will be protected and remediated to achieve such use (40 CFR 300.430(a)(1)(ii)(F)) in the absence of pretreatment. The fact that surface water is not currently being used or that no one currently plans to use this resource is not justification for not attaining or using criteria to protect the river.* *~~Even if the Willamette River were to be used as a domestic water source, which is not likely, that would only occur after adequate pretreatment to meet Safe Drinking Water Act standards and Oregon rules. Under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, but only with adequate pretreatment and natural quality that meets drinking water standards.~~ Therefore, the evaluation of ~~untreated~~ surface water as a potential future domestic water source~~, even under hypothetical future conditions,~~ is a ~~conservative~~ health protective approach and consistent with		LWR within the Study Area is not currently used as a domestic water source~~, nor are there plans to use surface water within the Study Area as a domestic water source in the future~~. According to the City of Portland, the primary domestic water source for Portland is the Bull Run watershed, which is supplemented by a groundwater supply from the Columbia South Shore Well Field (City of Portland 2008). In addition, the Willamette River was determined not to be a viable water source for future water demands through 2030 (City of Portland 2008). ~~Given that current knowledge of the City of Portland planning for water supply does not indicate that the reach of the Willamette River including the Study Area will be used for domestic purposes in the future.~~ ~~Even if the Willamette River were to be used as a domestic water source, which is not likely, that would only occur after adequate pretreatment to meet Safe Drinking Water Act standards and Oregon rules.~~ Under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, but only with adequate pretreatment and natural quality that meets drinking water standards. The use of the Willamette River as a domestic water source would only occur after adequate pretreatment to meet Safe Drinking Water Act standards and Oregon rules. As a result, the term hypothetical was used to describe the scenario, which was based on the use of untreated surface water. Therefore, the evaluation of untreated surface water as a domestic water source, even under hypothetical future conditions, is a conservative approach and is not based on current knowledge of future planned uses of the Willamette River within the Study Area as a domestic water source or based on Oregon rules that require adequate pretreatment. ~~an indication of current or reasonably anticipated future risks at the Study Area.~~"	Portland is the Bull Run watershed, which is supplemented by a groundwater supply from the Columbia South Shore Well Field (City of Portland 2008). In addition, the Willamette River was determined not to be a viable water source for future water demands through 2030 (City of Portland 2008). Therefore, the evaluation of surface water as a domestic water source is a conservative approach and is not based on current knowledge of future planned uses of the Willamette River within the Study Area as a domestic water."

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			EPA regulations and guidance ~~approach and is not an indication of current or reasonably anticipated future risks at the Study Area.~~""			
2k			July 16, 2010, **comment S132** §7.2.5, pp. 117-118 (directed change): "Modify the 3rd sentence in the 2nd paragraph as follows: "*In the case of the scenarios assessing the use of untreated surface water as a domestic water source, both the RME and CT scenarios represent ~~hypothetical~~ potential future exposures.*""	See comment resolution in 2a above.	Revised text in §7.2.5 (now §6.2.5). "In the case of the scenarios assessing the use of untreated surface water as a domestic water source, both the RME and CT scenarios represent hypothetical exposures."	Sentence deleted.
2l			July 16, 2010, **comment S136** §7.2.5.2, pp. 119-120 (directed change): "The following changes should be made in the 3rd paragraph in this section: *In addition to the direct contact scenarios mentioned above, risks were assessed from exposure to surface water as a ~~hypothetical~~ potential future domestic water source. This scenario assumes untreated surface water is used as a domestic water source ~~is drunk and bathed in~~ 350 days a year for 30 years (adult resident) or 6 years (child) ~~resident), using tap water ingestion rates. As with the transient scenario, this scenario is equally unlikely for residents in the area.~~ The LWR within the Study Area is not currently used as a domestic water source, but could be used as such in the future ~~nor are there any future plans to use the LWR within the Study Area as a domestic water source.~~*""	See comment resolution in 2a above.	Revised text in §7.2.5.2 (now §6.2.5.2). "In addition to the direct contact scenarios mentioned above, risks were assessed from exposure to surface water as a hypothetical future domestic water source. This scenario assumes untreated surface water is used as a domestic water source ~~drunk and bathed in~~ 350 days a year for 30 years (adult resident) or six years (child resident)~~, using tap water ingestion rates. As with the transient scenario, this scenario is equally unlikely for residents in the area~~. The LWR within the Study Area is not currently used as a domestic water source, ~~nor are there any future plans to use the LWR within the Study Area as a domestic water source~~ but could be used as such in the future."	Paragraph deleted.
2m			July 16, 2010, **comment S173** §8.0, p. 137 (directed change): "Revise the last bullet as follows: "*~~Hypothetical~~ Potential future resident – ~~Hypothetical direct~~ Future exposure to untreated surface water used as a domestic water source.*""	See comment resolution in 2a above.	Revised text in §8.0 (now §7.0). "~~Hypothetical future resident~~ Domestic Water User – Hypothetical direct exposure to untreated surface water used as a domestic water source"	"Domestic Water Use – Direct exposure to surface water used as a domestic water source"
3a	**The LWG objects to EPA's revisions deleting references to evaluations being done at the direction of EPA because these revisions are inconsistent with prior agreements between EPA and the LWG.**	This issue was not raised by EPA during development and finalization of in the Programmatic Work Plan.	July 16, 2010, **comment S28** §1.0, p. 12 (revise): "The document suggests that this report is somehow different from other risk assessments because EPA directed the use of conservative assumptions. In fact, risk assessments performed under guidance from other federal agencies, states, and even other countries, assess risks and inform risk management decisions based on assumptions that report risks in the upper range of those possible. The risk assessment for PH is thus typical in this regard. Accordingly, with the exception of the first sentence, the text in the third paragraph should be deleted."	LWG September 15, 2010 *General Responses to Directed Comments on BHHRA:* "As discussed at the August 20th and September 9th meetings, language stating that evaluations were done at the direction of EPA can remain in the revised BHHRA. Language implying opinion or judgment about the prudence of that direction will be removed." EPA September 22, 2010 *EPA General Responses to EPA Directed BHHRA and BERA Comments:* "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the	Revised text in §1.0. "The LWG has worked with the United States Environmental Protection Agency (EPA) to develop the methods and assumptions used in this BHHRA. At the direction of EPA, this BHHRA incorporates ~~conservative~~ assumptions to provide a health protective assessment of risks associated with contaminants present at the Site, which is consistent with EPA guidance on risk assessment (1989). For many of the exposure scenarios evaluated in this BHHRA, upper-bound literature values are used to quantify exposure due to the lack of site-specific exposure information. In some cases, the maximum detected concentrations are used to quantify long-term exposures. ~~While the use of maximum detected concentrations provides a health protective approach, it~~ which may not be representative of ~~conditions~~ ongoing exposures in the Study	"The LWG has worked with the United States Environmental Protection Agency (EPA) to develop the methods and assumptions used in this BHHRA. Consistent with EPA guidance (1989), this BHHRA incorporates assumptions to provide a health protective assessment of risks associated with contaminants present at the Site. The risk assessment for Portland Harbor is a baseline risk assessment in that it evaluates human health risks and hazards associated with contamination in the absence of remedial actions or institutional controls."

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
				proposed resolution described in LWG's general responses matches our understanding of the meeting outcome." Includes three unrelated clarifications.	Area. Therefore, the results of the BHHRA have a margin of conservatism built into the risk conclusions consistent with EPA guidance (1989). ~~The conservative assumptions about exposure and toxicity also affect the preliminary remediation goals (PRGs) and early activities in the Feasibility Study (FS).~~"	
3b			July 16, 2010, **comment S30** §1.2, p. 14 (directed change): "Modify the last paragraph in Section 1.2 as shown: *"The approach of this BHHRA is based on EPA (1989, 1991b, 2001a, 2004, 2005a) and Region 10 EPA (2000a) guidance.~~, except where further health protective assumptions were used at the request or direction of EPA.~~"* The risk assessment for PH follows EPA guidance and is not atypical or overly health protective for risk assessments done for a Superfund RI/FS."	See comment resolution in 3a above.	Revised text in §1.2. "The approach of this BHHRA is based on EPA (1989, 1991b, 2001a, 2004, 2005a) and ~~Region 10~~ EPA Region 10 (2000a) guidance. ~~except where further health protective assumptions were used at the request or direction of EPA~~ and direction from EPA. The approach is also consistent with DEQ guidance for HHRAs (DEQ 2000a, 2010)."	"The BHHRA is based on EPA (1989, 1991b, 2001a, 2004, 2005a) and EPA Region 10 (2000a) guidance, and is also consistent with DEQ guidance (DEQ 2000a, 2010)."
3c			July 16, 2010, **comment S45** §3.2.2 (revise): "Infant ingestion of mother's milk and ingestion and dermal contact with household uses of surface water should be added as potential exposure pathways to the bulleted list."	LWG November 18, 2010 *General Responses to EPA's Non-Directive Comment Key Issues on the BHHRA*: "This issue was addressed in the responses to EPA's Directive Comments." EPA December 8, 2010 *EPA General Responses to EPA Non-Directed RI, BHHRA and BERA Comments*: "EPA has reviewed the LWG responses, as summarized in the tables, and has determined that the vast majority of issues associated with addressing EPA's comments have been resolved. However, there were three comments for which the LWG did not agree to make the specified changes." Includes three unrelated comments and additional unrelated clarifications.	Revised text in §3.2.2. "The conceptual site model (CSM) for human exposures based on the current understanding of the Study Area and requirements from EPA is presented in Figure 3-1. The CSM graphically depicts possible sources of COPCs based on current information, possible COPC-affected media, mechanisms of COPC transfer between media, and the processes through which human receptors may be exposed to chemicals. Additional information on potential sources of COPCs is provided in Section 5 of the RI Report. Potentially complete exposure pathways were identified in the Programmatic Work Plan or based on subsequent requirements from EPA. In-water workers exposure to river sediment, transients exposure to shoreline seeps, divers exposure to surface water and in-water sediment, infant exposure via consumption of human milk for all receptors with bioaccumulative COPCs, and hypothetical future exposures of ~~residents~~ domestic water users to surface water were included as potentially complete pathways per requirements from EPA. Pathways that are potentially or hypothetically complete and may result in significant exposure, or for which significance is unknown, were evaluated quantitatively in this BHHRA, per direction from EPA. Pathways included at the direction of EPA include clam consumption, exposure to surface water and in-water sediment by a commercial diver, and hypothetical exposure to untreated surface water ~~as domestic water source~~ by a ~~hypothetical future resident~~ domestic water user."	"The conceptual site model (CSM) describes potential contaminant sources, transport mechanisms, potentially exposed populations, exposures pathways and routes of exposure. As discussed in Sections 4, 5, and 6 of the RI Report, contaminated media within the Study Area are sediment, water, and biota. Current and historical industrial activities and processes within the Study Area have led to chemical releases from either point or nonpoint sources, including discharges to the river from direct releases or via outfalls and groundwater within the Study Area. In addition, releases that occur upstream of the Study Area and atmospheric deposition from global, regional, and local emissions may also represent potential contaminant sources to the Study Area. Chemicals in sediment and water may be accumulated by organisms living in the water column or by benthic organisms in sediments. Fish and shellfish within the Study Area feeding on these organisms can accumulate chemicals in their tissues through dietary and direct exposure to sediment and water. Additional information on potential contaminant sources is provided in Section 4 of the RI Report, and a more detailed CSM is presented in Section 10. A graphical representation of the exposure CSM is presented on Figure 3-1."
3d			July 16, 2010, **comment S125** §7.2.3, p.	See comment resolution in 3a above.	Revised text in §7.2.3 (now §6.2.3). "Some of	"Some of the uncertainties associated

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
			115 (directed change): "Delete the following sentences: *~~"As required by EPA Region 10, this BHHRA included exposure scenarios that are not well documented, so it is unknown to what extent exposures currently occur, if at all, within the Study Area. In addition, this BHHRA evaluated risks associated with a hypothetical future scenario, which is not anticipated to reasonably occur in the future based on current information for the Study Area. The uncertainties associated with these potential and hypothetical exposure scenarios are discussed in the following subsections."~~* Consistent with EPA Superfund guidance, EPA and its partners chose only those scenarios that are reasonably anticipated to occur and are consistent with current statutory or regulatory requirements (e.g., designated beneficial use of the river as a source for drinking water)."		the exposure scenarios evaluated in this BHHRA have limited documentation regarding the actual extent of exposure to receptors in the Portland Harbor. These scenarios were included in this BHHRA at the direction of EPA Region 10. The uncertainties associated with these scenarios are discussed in the following subsections. ~~As required by EPA Region 10, this BHHRA included exposure scenarios that are not well documented, so it is unknown to what extent exposures currently occur, if at all, within the Study Area. In addition, this BHHRA evaluated risks associated with a hypothetical future scenario, which is not anticipated to reasonably occur in the future based on current information for the Study Area. The uncertainties associated with these potential and hypothetical exposure scenarios are discussed in the following subsections.~~"	with the exposure scenarios evaluated in the BHHRA are discussed in the following subsections."
3e			July 16, 2010, **comment S172** §8.0, p. 137 (revise): "Revise the first sentence in the second paragraph as follows: *"Populations evaluated in the risk characterization portion of the BHHRA were identified based on human activities that are known to occur now and/or which could occur in the future within the Study Area, ...""*	See comment resolution in 3c above.	Revised text in §8.0 (now §7.0). "The populations evaluated in the risk characterization portion of the BHHRA were identified based on human activities that are known to occur now and/or which could occur in the future within the Study Area, as described in the Programmatic Work Plan, or were directed by EPA for evaluation in this BHHRA."	"The populations evaluated in the BHHRA were identified based on human activities currently known to occur within the Study Area or could occur in the future, as described in the Programmatic Work Plan."
3f			EPA's comments on the 2009 Draft BHHRA did not include comments on the cited text in §1.2.		Text in §1.2. "Exposure scenarios that were not included in the Programmatic Work Plan were evaluated in this BHHRA based on direction from EPA. Specific agreements with and direction from EPA related to the approach for this BHHRA are documented in Attachment F1."	"Specific documents related to the approach for this BHHRA are presented in Attachment F1."
3g			EPA's comments on the 2009 Draft BHHRA did not include comments on the cited text in §3.1.		Text in §3.1. "The above populations were identified based on human activities that are known to occur within the Study Area, as described in the Programmatic Work Plan, or were required by EPA for evaluation in this BHHRA."	"The above populations were identified based on human activities know to occur within the Study Area, with the exception the use of surface water as a domestic water source."
3h			EPA's comments on the 2009 Draft BHHRA did not include comments on the cited text in §3.3.2.2.		Text in §3.3.2.2. "The diver exposure scenarios were directed by EPA in a memorandum regarding the *Proposed Commercial Diver Exposure Scenario for the Portland Harbor Risk Assessment* (EPA 2008c)."	Sentence deleted.
3i			EPA's comments on the 2009 Draft BHHRA did not include comments on the cited text in §5.2.3.3.2.		Text in §5.2.3.3.2. "The commercial diver in a dry suit was not evaluated for CT exposure, as directed by EPA."	"a CT evaluation was not done for a commercial diver in a dry suit."
4a	**The LWG objects to EPA's revisions that modify the Study Area boundaries because these revisions are inconsistent with prior agreements between EPA and**	This issue was not raised by EPA during development and finalization of in the Programmatic Work Plan.	No comments.	April 15, 2009 table, *Outstanding Portland Harbor RI/FS Issues, Status as of 4/15/2009*: #22 (Study Area Boundary): "On 6/11/08 EPA and LWG agreed that the site-wide risk scenarios would be	Text in §1.3. "The approximate 10-mile portion of Portland Harbor from RM 1.9 to 11.8 is referred to as the Study Area (Map 1-1)." Text in §5.2.2. "In addition to calculating risks from in-water sediment exposure within the	"The approximate 11-mile portion of Portland Harbor from RM 0.8 to 12.2 is referred to as the Study Area (Map 1-1)."

Table 2: General categories of LWG objections to the EPA June 22, 2012 revisions[1]:

Issue Number	Basis for LWG objection	April 23, 2004 Programmatic Work Plan	EPA Comment on 2009 Draft BHHRA	LWG/EPA Comment Resolution	May 2, 2011 Draft Final BHHRA (redline)	EPA June 22, 2012 Revised BHHRA
	the LWG.			developed for the Study Area from RM 2 to RM 11.8 and that separate EPCs and baseline risk evaluations would be prepared for the areas between RM 1 and RM2, upper Multnomah Channel, and RM 11.8 to RM 12.2."	Study Area (which includes exposure areas from RM 1.9 to RM 11.8, including Swan Island Lagoon), risks from in-water sediment exposure were calculated for three river segments outside of the Study Area: the downstream reach (RM 1.0-1.9), the downtown river segment (RM 11.8 – 12.2), and Multnomah Channel."	Text deleted.
5a	**The LWG objects to EPA's revisions that were not the subject of prior comments.**		July 16, 2010 Cover Letter: "EPA has attempted to provide clear direction on the specific revisions that are needed to resolve the comments." "EPA's comments are focused on areas of the report that were deficient, and changes are needed to make the report acceptable to EPA."		The Executive Summary was revised in accordance with EPA's July 16, 2010 comments, which included 25 specific comments, of which 3 were directed changes, on the Executive Summary.	Executive Summary section deleted
5b					The Conclusions section was revised in accordance with EPA's July 16, 2010 comments, which included 2 specific comments, of which one was a directed change, on the Conclusions.	Conclusions section deleted
5c						The above are two specific examples; throughout the 200-page document, there are extensive additional directed changes to the text, table, and figures that were not part of the July 16, 2010 comments.

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July 23, 2012 LWG Notice of Objection to EPA Notice of Non-Compliance and Directed Revisions to the Portland Harbor Draft Final Baseline Human Health Risk Assessment and Request for Dispute Resolution
Lower Willamette River, Portland Harbor Superfund Site
USEPA Docket No: CERCLA-10-2001-0240